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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,095	04/23/2004	Sciichi Ono	8029/84010	7519
42798	7590	10/09/2007		
FITCH, EVEN, TABIN & FLANNERY			EXAMINER	
P. O. BOX 18415			FITZGERALD, JOHN P	
WASHINGTON, DC 20036			ART UNIT	PAPER NUMBER
			2856	
			MAIL DATE	DELIVERY MODE
			10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/830,095	ONO, SEIICHI	
	<b>Examiner</b>	<b>Art Unit</b>	
	John Fitzgerald	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 August 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 4-12, 14, 16 and 18-60 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 13, 15 and 17 is/are rejected.
- 7) Claim(s) 2 and 3 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 July 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/10/06; 1/19/06; 8/27/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 4-12, 14, 16 and 18-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 27 August 2007. Applicant's election with traverse of Figure 7 in the reply filed on 27 August 2007 is acknowledged. Applicant has not provided grounds/arguments for the traversal, and as such, is considered to be an election without traverse. Applicant should note that claim 21 recites, in part, "detector body formed separately from the leak detection unit..." The "detector body" is not represented in elected Figure 7, and as such, is withdrawn from consideration by the Examiner. The claims currently under examination are: 1-3, 13, 15 and 17.

The requirement is still deemed proper and is therefore made FINAL.

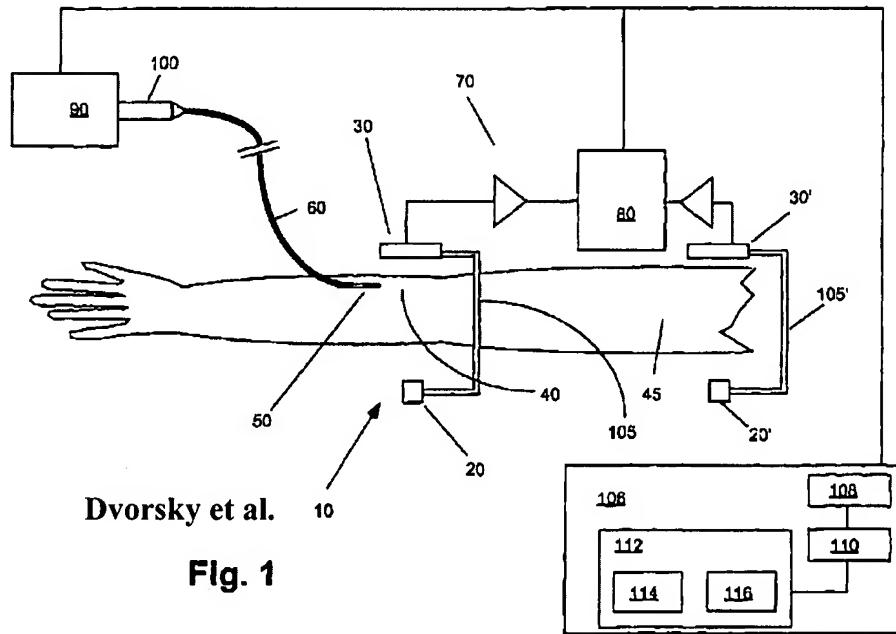
### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,047,058 to Dvorsky et al. and US 6,295,873 to Condreva. Dvorsky et al. disclose a leak (extravasation) detector for detecting a liquid injected through a needle (50) into a blood vessel near the surface of a human body (see Fig. 1 below) including a pulse generating means (i.e. energy source for

generating waves of electromagnetic radiation (x-ray, gamma ray) or ultrasound (i.e. sound/sonic) signals are emitted towards the human body and the subsequent reflected signals are detected/measured and then an imaging apparatus is used to display (i.e. warning result/indicator) the results to indicate the occurrence of a leak/extravasation. However, Dvorsky et al. do not expressly disclose waves emitted a predetermined wavelength; a interval measuring means to measure a time interval between the emission and reception/detection of the pulsed signals; a difference calculating means to calculate the difference between the measured time interval and a predetermined reference time interval; and a difference comparing means for comparing the difference with a predetermined acceptable range and thus issuing a leak notification/warning if exceeded (as recited in claim 1).



4. Condreva discloses an ultrasonic sensor and method of use for measuring the transit time (i.e. interval) of reflected/transmitted pulsed sound waves by a pulse generator (pulse generating means) (2) through a sample (or, "In the field of medicine, specific properties of bodily fluids

can be monitored" (Condreva: col. 8, lines 36-37)), wherein a interval measuring means (i.e. timing circuit/interval counter), representing small changes in the velocity of sound transmitted, over small time intervals to determine the presence of constituents in a sample (i.e. a change in composition/property of the sample to which the pulsed wave signals are transmitted through/reflected from); the transit time measured and compared to (i.e. difference calculating means, as recited in claim 1) a predetermined reference time (i.e. predetermined interval, as recited in claim 1), which is determined by a 'pre-calibration' procedure, thus determining the presence/change in the sample. Condreva further discloses an interval storing means (see Condreva, claim 6) for storing the predetermined transit/reference time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the leak/extravasation detector disclosed by Dvorsky et al., by employing the technique of measuring the transit time of a pulsed acoustic/sound wave signal, as disclosed by Condreva, thus providing a system capable of operating in environments of extreme ranges of temperature, pressure and pH, is easily integrated in to existing systems, and does not require constant hands-on/manual adjustment by an operator (Condreva: col. 8, lines 43-62). In specific regards to the limitation of "at a predetermined wavelength" recited in instant claim 1, all signals/pulses generated by a signal generating system/apparatus in both the Dvorsky et al. and Condreva references inherently have specific wavelength(s) (typically predetermined based on what wavelength and/or frequency range the chosen signal is generated, i.e. visible/non-visible electromagnetic light range, sonic and/or ultrasonic, etc.), thus meeting this particular limitation of the claim. Furthermore, the choice of wavelength appears to be irrelevant to the function of the instant

invention, since the ‘transit time/interval’ is only measured/determined, which is independent of the wavelength of the signal generated/reflected.

5. Claims 13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,047,058 to Dvorsky et al. and US 6,295,873 to Condreva as applied to claim 1 above, and further in view of US 4,877,034 to Atkins et al. Dvorsky et al. and Condreva disclose a leak detector having all of the elements stated previously, including the employment of all types of signal waves including sonic and electromagnetic radiation, which includes light, and thus infrared radiation/rays, and in employment in the ‘field of medicine.’ Although Dvorsky et al. and Condreva do not specifically disclose the employment of an infrared rays (instant claim 13), (however, infrared rays are inherently included in the spectrum of ‘electromagnetic radiation’) at a specific wavelength (note: all types of waves, electromagnetic, sonic, etc. inherently have a specific or range of wavelengths and/or frequencies, as pointed out by the Examiner in paragraph 4 above) through a particular organ of a human body (instant claim 15), they do claim that the device can be employed in the field of medicine, and it is well known in the art that ultrasound devices are employed in the medical field for examining internal organs of humans. Atkins et al. disclose a leak detector employing infrared rays exposing a portion of a human body and examining the changes in those wavelengths and relating them to electrical signals to determine if a leak has occurred. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ infrared rays as the particular ‘type’ of electromagnetic radiation, at a specific wavelength (as recited in claims 13, 15 and 17), as taught by Atkins et al., modifying the leak detector disclosed by Dvorsky et al. and Condreva, thus providing a leak detecting device that will not be triggered by ambient noise, light and temperature changes nor

by patient activities (Atkins et al.: col. 2, lines 33-36) during the examination of internal organs or otherwise.

***Allowable Subject Matter***

6. Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

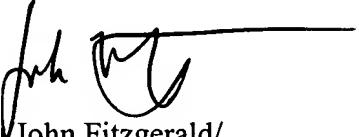
***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant is invited to review PTO form 892 accompanying this Office Action listing Prior Art relevant to the instant invention cited by the Examiner.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Fitzgerald whose telephone number is (571) 272-2843. The examiner can normally be reached on Monday-Friday from 7:00 AM to 3:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams, can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR.

Art Unit: 2856

only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John Fitzgerald/  
09/26/2007